

**REMARKS**

Claims 1-21, 137-158 and 159-173 are pending in the present application.

By this Amendment, claims 1, 137 and 159 are amended, claims 7, 8, 146, 147, 165 and 166 are cancelled without prejudice or disclaimer and claims 174-179 are added. No new matter has been added by the amendments. Applicants respectfully request reconsideration in view of the above amendments and following remarks.

**SUMMARY OF ACTION**

Claims 1-21, 137-158 and 159-173 are pending in the present application. Claims 22-136 and 151-158 were previously withdrawn. Claims 1-4, 7-8 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kuroda (JP 58-140013). Claim 1-4, 7-8, 11, 137-140, 143-148, 150, 159-167 and 169 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroda in view of Margraf (archives of Surgery, 1977; 112 (6): 699-704) and Bar-On (U.S. Patent No. 5,122,533). Claim 1-21, 137-150 and 159-173 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroda in view of Margraf, Bar-On and further in view of Grollier (U.S. Patent No. 4,767,618). Claims 1-21, 137-150 and 159-173 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-26 of co-pending U.S. Patent Application No. 10/322,797. Claims 1-21, 137-150 and 159-173 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,673,826 and claims 1-25 of U.S. Patent No. 6,531,500.

**Claim Rejections - 35 U.S.C. § 102(b)**

Claims 1-4, 7-8 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kuroda (JP 58-140013).

The Office Action states, among other things, that Kuroda “teaches compositions and methods of applying a composition comprising allantoin, an anionic emulsifier, and a wax” and that Kuroda further discloses “compositions having prolonged stability of about 90 days when pH levels of the composition is adjusted below 5.5.” The Office Action also states that Kuroda also teaches “that emulsion preparations such as ointments and creams may contain suitable anionic surfactants such as sodium alkylsulfates” and “that allantoin is an old compound which is commonly used for treatment of various skin ailments such as cuts, burns, as well as, inflammatory skin conditions such as eczema.”

Kuroda discloses an allantoin-containing composition having a pH of about 5.5. Kuroda, however, specifically indicates that if the topical composition as disclosed and claimed is “adjusted below pH 4, it is not desirable for the skin...” (p. 6). Kuroda also states that results for the allantoin composition were excellent at approximately pH 5.0, but that “the allantoin content was found to be reduced a pH 6-7.” (p. 6). In that regard, Table 2 in Kuroda (pg. 6) evidences a drop in allantoin concentration, and hence effectiveness, at a pH values greater than 5. Consequently, the composition disclosed in Kuroda is only effective within a very narrow pH range. Additionally, Kuroda does not teach a method of treating epidermolysis bullosa.

In particular, Kuroda does not teach a composition comprising “a method of treating epidermolysis bullosa comprising applying to the skin of patients in need thereof an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising (a) allantoin; (b) an emulsifier system including (i) an acidic wax; and (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water; and (c) an acid to adjust the pH of the composition to a value in the range of from about 3.0 to about 6.0, wherein the allantoin is stable in the emulsion across the pH

range from about 3.0 to about 6.0” as recited by independent claim 1. Furthermore, Kuroda specifically teaches away from the invention recited in independent claim 1 by indicating the disclosed compositions are ineffective below a pH of 4.0 and have a reduction in allantoin concentration at pH values between 6-7. Kuroda, therefore, does not anticipate independent claim 1.

Claims 2-4 and 11 depend from independent claim 1 (claims 7 and 8 have been cancelled by this Amendment). It is respectfully submitted that dependent claims 2-4 and 11 are distinguishable over Kuroda for at least the same reasons described above for independent claim 1 and for the additional features they recite. Thus, withdrawal of the rejections of independent claim 1 and dependent claim 2-4 and 11 under 35 U.S.C. §102(b) is respectfully requested.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claim 1-4, 7-8, 11, 137-140, 143-148, 150, 159-167 and 169 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroda in view of Margraf and Bar-On.

Applicant reiterates the remarks set forth above regarding Kuroda as applied to claims 1-4 and 11. Additionally, Kuroda fails to teach “a method of treating epidermolysis bullosa comprising applying to the skin of patients in need thereof an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising: (a) allantoin; (b) a carbohydrate polymer; and (c) an emulsifier system comprising: (i) an acidic wax; and (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water; wherein the pH of the composition is between about 3.0 and about 6.0 and wherein the allantoin is stable in the emulsion across the pH range from about 3.0 to about 6.0” as recited in independent claim 137 and “a method of treating epidermolysis bullosa comprising applying to the skin of patients in need thereof an allantoin-containing

composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising: (a) allantoin in a concentration of at least about 2.5%; and (b) an emulsifier system comprising: (i) an acidic wax; and (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water; wherein the pH of the composition is between about 3.0 and about 6.0 and wherein the allantoin is stable in the emulsion across the pH range from about 3.0 to about 6.0” as recited in independent claim 159.

The Office Action asserts that Margraf and Bar-On teach “the therapeutic benefits of allantoin in treating necrotic tissue.” The Office Action asserts that Margraf teaches, among other things, that allantoin “stimulates the growth of healthy tissue and debies necrotic tissue” and that it teaches “the efficacy of allantoin containing cream in treating diabetic ulcers in 92 patients” as well as the treatment of vascular skin ulcers. The Office Action asserts that Bar-On “teaches suitable allantoin delivery systems comprising allantoin and an anionic surfactant for treatment of necroting tissues” but does not teach the use of bees wax.

Margraf and Bar-On fail to supply the deficiencies of Kuroda. Thus, the combination of Kuroda, Margraf and Bar-On fails to provide the invention recited in independent claims 1, 137 and 159. Moreover, Kuroda, Margraf and Bar-On do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in independent claims 1, 137 and 159. Thus, it is respectfully submitted that Kuroda, Margraf and Bar-On fail to teach or suggest the invention recited in independent claims 1, 137 and 159. Therefore, withdrawal of the rejection of independent claims 1, 137 and 159 and dependent claims 2-4, 11, 138-140, 143-145, 148, 150, 160-164, 167 and 169 under 35 U.S.C. § 103(a) is respectfully requested.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claim 1-21, 137-150 and 159-173 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroda in view of Margraf, Bar-On and further in view of Grollier (U.S. Patent No. 4,767,618).

Applicant reiterates the remarks set forth above regarding Kuroda in view of Margraf and Bar-On as applied to independent claims 1, 137 and 159 and dependent claims 2-4, 11, 138-140, 143-148, 150, 160-167 and 169.

The Office Action asserts that Grollier “is used to provide the deficiency of the combined teachings of JP ‘013, Margraf and Bar-on.” The Office Action states that Grollier discloses oil-in-water emulsion compositions containing, among other things, allantoin, herbal components (*e.g.*, St. John’s wort, chamomile, arnica, or witch hazel), thickening agents (*e.g.*, guar gum, cellulose derivatives), anionic surfactants, propylene glycol and perfume.

Grollier fails to supply the deficiencies of Kuroda, Margraf and Bar-On. In particular, Grollier et al. does not teach methods of treating epidermolysis bullosa with the instantly claimed compositions. Moreover, Kuroda, Margraf, Bar-On and Grollier do not provide the requisite motivation to combine and/or modify their teachings to arrive at the invention recited in independent claims 1, 137 and 159. Thus, it is respectfully submitted that Kuroda, Margraf, Bar-On and Grollier fail to teach or suggest the invention recited in independent claims 1, 137 and 159. Therefore, withdrawal of the rejection of independent claims 1, 137 and 159 and dependent claims 2-6, 9-21, 138-145, 148-150, 160-164 and 167-173 under 35 U.S.C. § 103(a) is respectfully requested.

**Double Patenting**

Claims 1-21, 137-150 and 159-173 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-26 of co-pending U.S. Patent Application No. 10/322,797. Claims 1-21, 137-150 and 159-173 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,673,826 and claims 1-25 of U.S. Patent No. 6,531,500. A Terminal Disclaimer is filed herewith in order to obviate the rejection over claims 13-26 of co-pending U.S. Patent Application No. 10/322,797, 1-10 of U.S. Patent No. 6,673,826 and claims 1-25 of U.S. Patent No. 6,531,500 with respect to pending claims 1-21, 137-150 and 159-173. Accordingly, withdrawal of this rejection is respectfully requested.

**CONCLUSION**

In view of the foregoing, Applicant respectfully requests the reconsideration and timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicant's undersigned representative to expedite prosecution.

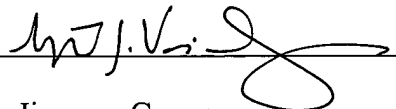
If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1349. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

**HOGAN & HARTSON LLP**

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**HOGAN & HARTSON LLP**  
555 13<sup>th</sup> Street N.W.  
Washington, D.C. 20004  
Telephone: (202) 637-6807  
Facsimile: (202) 637-5910  
**Customer No. 24633**

By: 

Celine Jimenez Crowson  
Registration No. 40,357

Ajit J. Vaidya  
Registration No. 43,214

William T. Slaven IV  
Registration No. 52,228

Attachment: Terminal Disclaimer